

Case Study: Disaster Recovery

During an ICH stability study crisis, a pharmaceutical company activated their Q1 Scientific disaster recovery plan. Samples were saved, timelines remained intact, and quality assurance was maintained thanks to a seamless sample transfer and expert support from Q1 Scientific.

Challenge

A pharmaceutical company was conducting stability testing on a new drug product intended to treat a rare, life-threatening disease. The product was in the final stage of development and on track to be submitted for regulatory approval. At one point in their ICH stability study, the company discovered that one of its stability chambers had malfunctioned due to a faulty sensor that caused the temperature and humidity levels to fluctuate erratically. The malfunction continued unnoticed for several hours, affecting hundreds of samples. The pharmaceutical company was unable to leverage its own in-house backup equipment, as all redundant chambers were already at full capacity. The pharmaceutical company faced the risk of losing valuable data and samples, delaying its regulatory filing, and compromising its product quality and patient safety.

“Q1 Scientific has provided us with an excellent resource for stability storage. The staff are very knowledgeable and friendly and show a great interest in our business. The security provided for critical samples is first class and allows us to know that our samples will be kept at the required conditions for the duration of our stability studies”

Leading Pharmaceutical Company

Solution

The pharmaceutical company was already an existing Q1 Scientific client and had space reserved in the event of an emergency to transfer samples within a 24-hour timeframe of the condition failure, remaining in compliance with ICH guidelines. This proactive approach of the customer reserving emergency backup storage space at Q1 Scientific is an example of many of our clients' risk mitigation strategies, highlighting the benefits of having a disaster recovery plan that includes a contingency agreement with industry leaders who offer a reliable and compliant stability storage service. As a result of our partnership and successful sample transfer to Q1 Scientific, the company was able to continue its stability testing program without interruption or deviation.

Outcome

By having a disaster recovery plan that involved Q1 Scientific as their backup/disaster recovery stability storage provider, the pharmaceutical company:

- Saved significant time and cost resources by avoiding the need to repeat or extend the stability testing program.
- Kept their regulatory filing on track, bringing the product to market as planned.
- Ensured the integrity and safety of their stability samples and data.
- Maintained their product quality and patient safety standards.

